

## **REMARKS**

Applicants thank the Examiner for the personal interview granted on January 20, 2004. As discussed during the interview, Applicants have amended independent claims 1, 19, and 24, to indicate that the invention is directed to a wound dressing, and methods of treating a wound using a dressing, comprising a protein-containing fibrous component made of protein fibers. In addition, to clarify that the fibers in the fibrous component are protein fibers such as wool or silk, instead of non-protein fibers such as cotton, claims 6-9 and claims 30-31 have been canceled. Minor changes have been made to several of the other dependent claims to make them consistent with the independent claims.

Additionally, during the interview, Applicants made the Examiner aware of a related application currently under examination, having Serial No. 10/017,058. A supplemental IDS that includes references cited by the Examiner in the related case accompanies this response.

Applicants request that the Examiner reconsider the rejections of the claims in light of the foregoing amendments and the following arguments and allow the pending claims.

**A. Rejection of claims 1-19 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention.**

The Examiner rejected claims 1-19 under 35 U.S.C. § 112, second paragraph, as indefinite, stating that the phrase "said wound site" recited in claim 1 (and in subsequent claims) lacks proper antecedent basis.

Applicants have amended independent claims 1, 19, and 24 as suggested by the Examiner by replacing the word “said” with the word “the”. In light of these amendments, the Examiner is respectfully requested to withdraw the rejection of claims 1-19 under 35 U.S.C. § 112, second paragraph, as being indefinite.

**B. Rejection of claims 1, 3, 4, 6-8, 19, 22-24, 26, 27, and 29-31 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,334 to Meyer-Ingold et al.**

The Examiner rejected claims 1, 3, 4, 6-8, 19, 22-24, 26, 27, and 29-31 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,334 to Meyer-Ingold et al. (“Meyer-Ingold”).

The Examiner states that Meyer-Ingold discloses wound coverings that remove interfering factors, such as proteases. According to the Examiner, certain substances that interact with the interfering factors are covalently bonded to a carrier material that is applied to the wound. The Examiner further states that Meyer-Ingold also discloses the use of growth factors in combination with the interfering factors to improve the healing process. The Examiner points out that Meyer-Ingold specifically discloses that wound dressings known in the art, including cotton-wool materials, can be modified by covalently bonding the trapper molecules (the bonding substances) to the dressing material and simultaneously applying substances that promote wound healing, such as growth factors, to the wound.

While Meyer-Ingold does disclose the use of cotton-wool dressings, which contain a protein-containing component (wool) and a non-proteinaceous component (cotton), there is no disclosure of a dressing containing a protein-containing fibrous component consisting essentially of protein fibers, as required by the amended claims

presented herein. The amended method claims require that one select a protein-containing fibrous component that consists essentially of protein fibers and then form a wound dressing containing the protein-containing fibrous component. It would be understood by one of skill in the art that the dressing itself may contain other components, such as adhesives, protective coverings, and the like in order to make the dressing itself useable. However, the fibers of the fibrous component are confined to protein fibers, to the exclusion of non-protein fibers.

Therefore, in light of the above amendment and arguments, the Examiner is respectfully requested to withdraw the rejection of claims 1, 3, 4, 6-8, 19, 22-24, 26, 27, and 29-31 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,156,334 to Meyer-Ingold et al.

**C. Rejection of claims 1, 2, 4-7, 10-14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0064551 A1 to Edwards et al. in view of U.S. Patent No. 5,158,555 to Porzilli.**

The Examiner rejected claims 1, 2, 4-7, 10-14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0064551 A1 to Edwards et al. (“Edwards”) in view of U.S. Patent No. 5,158,555 to Porzilli (“Porzilli”).

The Examiner states that Edwards discloses the use of cotton cellulose and a dialdehyde, which the Examiner states is a protein, based on the disclosure of U.S. Patent No. 4,335,017 to Miles et al. (“Miles”). The Examiner also states that Edwards fails to teach the step of selecting at least one protein from the group consisting of growth factors, cytokines, and chemokines for application to the wound site, and that

Porzilli discloses a wound dressing having a protein-containing fibrous component and epidermal growth factor.

Applicants have provided with this response a declaration under 37 C.F.R. § 1.131 executed by Jason P. McDevitt, an inventor of the present invention, swearing behind the February 29, 2000, priority date of the Edwards published application.

Edwards is not available as prior art under 35 U.S.C. § 102. Therefore, the Examiner is respectfully requested to withdraw the rejection of claims 1, 2, 4-7, 10-14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0064551 A1 to Edwards et al. in view of U.S. Patent 5,158,555 to Porzilli.

**D. Rejection of claim 9 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,156,334 to Meyer-Ingold et al. in view of U.S. Patent No. 5,856,245 to Caldwell et al.**

The Examiner rejected claim 9 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,156,334 to Meyer-Ingold et al. ("Meyer-Ingold") in view of U.S. Patent No. 5,856,245 to Caldwell et al. ("Caldwell").

Claim 9 has been canceled by Applicants in the amendment presented herein, thereby mooting this rejection.

**E. Rejection of claims 16 and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,156,334 to Meyer-Ingold et al.**

The Examiner rejected claims 16 and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,156,334 to Meyer-Ingold et al. ("Meyer-Ingold").

The Examiner states that Meyer-Ingold fails to disclose that the growth factor is in the form of an ointment, lotion, solution, or gel, and that, absent a critical teaching or

a showing of unexpected results, the form of the growth factor would be an obvious design choice.

Applicants have, previously in this response, distinguished the present invention from the wound dressing taught by Meyer-Ingold (see pages 8-9 herein).

Therefore, in light of those arguments presented previously, the Examiner is respectfully requested to withdraw the rejection of claims 16 and 21 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,156,334 to Meyer-Ingold et al.

**F. Rejection of claims 24, 25, 28, and 32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,158,555 to Porzilli.**

The Examiner rejected claims 24, 25, 28, and 32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,158,555 to Porzilli (“Porzilli”).

The Examiner states that Porzilli discloses a wound dressing comprising a protein-containing fibrous component (silk gauze) and at least one growth factor (epidermal growth factor).

The gauze layer (20) of the Porzilli dressing is not designed to be in direct contact with the wound site, as required by the newly-amended claims of the present invention. Intervening layers of an absorbent pad (18) and a non-stick material (22) are present between the gauze layer and the wound itself. Based on the disclosure of Pozilli, the purpose of the gauze layer is “to provide protection against macro foreign particles once the tear perforated cover 14 is removed” and the gauze layer “is placed directly adjacent to the macro ventilation perforations 12” (col. 2, lines 45-48).

Therefore, the gauze is present to inhibit the entry of foreign particles from the outside, and is not in direct contact with the wound. The gauze layer cannot then sequester

proteases from the wound site, as required of the protein-containing fibrous component in the dressing of the present application.

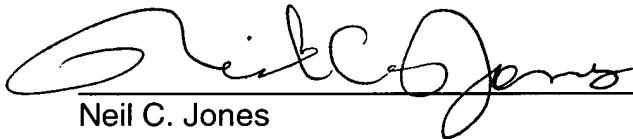
Therefore, in light of the above amendment and arguments, the Examiner is respectfully requested to withdraw the rejection of claims 24, 25, 28, and 32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,158,555 to Porzilli.

In sum, in view of the foregoing amendment and arguments, we respectfully submit that the rejected claims are patentably distinct over the references cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

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Date



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